DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 23, 2014

Zimmer Spine, Incorporated
Ms. Donna M. Semlak
Senior Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K141500
Trade/Device Name: Optio-C™ Anterior Cervical System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ, OVE
Dated: August 12, 2014
Received: August 13, 2014

Dear Ms. Semlak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141500

Device Name
Optio-C™ Anterior Cervical System

Indications for Use *(Describe)*
When Optio-C Anterior Cervical Plate is used with structural allograft/autograft it is intended for one-level anterior screw fixation of the cervical spine (C2-T1). The implant has been designed for use with structural allograft/autograft to provide stabilization as an adjunct to cervical fusion. Indications for use of the Optio-C Anterior Plate with structural allograft/autograft include degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion. The Optio-C Anterior Cervical Plate is intended to be used with a structural allograft/autograft and with three Optio-C bone screws.

When Optio-C Anterior Cervical Plate is used with an Optio-C PEEK IBF Spacer it becomes an Optio-C Anterior Cervical Intervertebral Body Fusion Device (IBFD), indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Degenerative disc disease (DDD) is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Optio-C IBFD is comprised of one Optio-C PEEK IBF Spacer, one Optio-C Anterior Cervical Plate and three Optio-C bone screws.

The Optio-C IBFD is to be used with autograft and implanted via an open, anterior approach in patients who have had six weeks of non-operative treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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zimmer spine	**510(k) SUMMARY** ***Optio-C™* Anterior Cervical System**

Date of Summary Preparation:	September 16, 2014
Submitter:	Zimmer Spine, Inc. 7375 Bush Lake Road Minneapolis, MN 55439 USA
Establishment Registration Number:	2184052 (Minneapolis)
Company Contact (Primary):	Donna M. Semlak Senior Regulatory Affairs Specialist Email: Donna.Semlak@zimmer.com Office: 952.857.5643 Email Fax: 952.857.5843
Trade Name(s):	*Optio-C*™ Anterior Cervical System
Device Names(s):	*Optio-C*™ Anterior Cervical Plate System *or* *Optio-C*™ Anterior Cervical PEEK Intervertebral Body Fusion Device (IBFD)
Device Classification:	Class II
Regulation Number and Product Code(s):	21 CFR § 888.3060 / KWQ *Cervical; Spinal Fixation System* 21 CFR § 888.3080 / OVE *Intervertebral Fusion Device with Integrate Fixation*

This submission is for the Optio-C Anterior Cervical Plate System, which is a component of the Optio-C Anterior Cervical System.

Predicate Devices:

Optio-C Anterior Cervical Plate System predicates were identified to address the intended uses, mechanical functions and performance attributes of each system. The predicate information is listed in the following table:

***Optio-C* Anterior Cervical System Predicate Device Name**	**Product Code**	**FDA 510k Number Clearance Date**
Synthes® Spine Anterior CSLP System Synthes Spine	KWQ 21 CFR § 888.3060	K031276 Cleared July 2, 2003
		K030866 Cleared April 18, 2003
		K971883 Cleared Oct 16, 1997
Trinica® Anterior Cervical Plate System Zimmer Spine, Inc.	KWQ 21 CFR § 888.3060	K012305 Cleared August 22, 2001

General Device Description:

The ***Optio-C Anterior Cervical System*** consists of two different configurations, an *Optio-C* Anterior Cervical PEEK Intervertebral Body Fusion Device (IBFD) (K132894, SE on January 16, 2014) and the subject of this submission, the *Optio-C* Anterior Cervical Plate System. Both configurations share the same cervical plate, bone screws and instrumentation and are used only in anterior surgical procedures and at the same spinal level of C2 to T1.

The subject cervical plate and bone screws of this submission are designed for use with structural allograft or autograft and is supplied sterile to the end user. The bone screws and instrumentation are supplied non-sterile and are intended to be sterilized by the end user.

The cervical plate with an *Optio-C* PEEK IBF Spacer or an allograft/autograft is placed in the cervical disc space, flush with the adjacent vertebral bodies. Bone screws pass through the screw holes of the plate and affix to bone to help prevent implant migration. The implant construct can be implanted in two orientations: Standard orientation, two screws cephalic and one screw caudal or Inverted orientation, one screw cephalic and two screws caudal.

The *Optio-C* Anterior Cervical Plate System is a stand-alone system designed to provide structural stability in skeletally mature individuals following discectomy. The implants are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Screws are inserted through the anterior titanium portion of the implant into adjacent vertebral bodies for bony fixation. The *Optio-C* Anterior Cervical Plate System is used with structural bone graft material and is manufactured from Titanium with Titanium bone screws that allow intradiscal fixation to the vertebral body. The superior and inferior surfaces of the implant have a pattern of ridges that provide increased stability and help prevent migration of the device.

The *Optio-C* Anterior Cervical System is provided for single use only.

Indications for Use:

The *Optio-C* Anterior Cervical System includes the following Indications for Use.

***Optio-C* Anterior Cervical System**

When Optio-C Anterior Cervical Plate is used with structural ***allograft/autograft*** it is *intended for one-level anterior screw fixation of the cervical spine (C2-T1). The implant has been designed for use with stuctural allograft/autograft to provide stabilization as an adjunct to cervical fusion. Indications for use of the Optio-C Anterior Plate with structural allograft/autograft include degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion. The Optio-C Anterior Cervical Plate is intended to be used with a structural allograft/autograft and with three Optio-C bone screws.*

When Optio-C Anterior Cervical Plate is used with an ***Optio-C PEEK IBF Spacer*** *it becomes an Optio-C Anterior Cervical Intervertebral Body Fusion Device (IBFD), indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Degenerative disc disease (DDD) is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Optio-C IBFD is comprised of one Optio-C PEEK IBF Spacer, one Optio-C Anterior Cervical Plate and three Optio-C bone screws.*

The Optio-C IBFD is to be used with autograft and implanted via an open, anterior approach in patients who have had six weeks of non-operative treatment.

Summary of Technological Characteristics:

The technological characteristics for the *Optio-C* Anterior Cervical Plate System are similar to the predicate devices in terms of design, dimensions, intended use, materials, and performance characteristics.

Summary of Performance Testing:

Non-clinical testing of the components comprising each configuration of the subject *Optio-C*™ *Anterior Cervical Plate System* were assessed and tested appropriately to design controls; i.e. design verification. The test results conclude the *Optio-C*™ *Anterior Cervical Plate System* to be substantially equivalent to the predicate devices listed above.

- Bench Testing for the cervical plate was conducted per ASTM 1717 for Static Torsion, Static and Dynamic Compression Bending, confirming the *Optio-C* Anterior Cervical Plate System performance is acceptable for its intended use; the same intended use as the predicate Synthes CSLP and Trinica devices.
- Design Validation / Cadaver Testing was conducted to ensure the *Optio-C* Anterior Cervical Plate System performance is acceptable for its intended use and to ensure substantial equivalence to the predicate(s).
- Biomechanical cadaveric testing was conducted.

- Gamma Sterilization was conducted for sterile implant components under ISO 11137 and ISO 11737.
- Packaging Sterility Testing was conducted per ISO 11607 to ensure packaging materials maintain a sterile barrier.
- Sterilization was conducted for sterilizing at the end user facility under ISO 17665 and AAMI TIR12 to ensure equivalent to the predicate devices. Dry time and cleaning instructions will be assessed and yield similar (substantially Equivalent) to the predicate devices.
- Biocompatibility Assessment per ISO 10993-1 was conducted to ensure the *Optio-C* System materials are biocompatible based with the same type materials to the predicate devices.

The *Optio-C* Anterior Cervical Plate System performance, intended use and fundamental scientific technology remain unchanged from the predicate devices. The implant construct design does not change the stabilization fixation of the cervical vertebra found in the predicate devices. The *Optio-C* Anterior Cervical Plate is substantially equivalent to the predicate devices, a traditional anterior cervical plate.